IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In re Testosterone Replacement Therapy Products Liability Litigation Coordinated Pretrial Proceedings	)	**Case No. 14 C 1748** **MDL No. 2545**
(This document applies to *Papandrea v. AbbVie*, Case No. 14 C 8948)	)	

CASE MANAGEMENT ORDER NO. 132
(Memorandum Opinion and Order on AbbVie's motion to exclude specific causation testimony of Dr. Hossein Ardehali and motion for summary judgment in *Papandrea v. AbbVie*, Case No. 14 C 8948)

MATTHEW F. KENNELLY, District Judge:

Plaintiffs in this multidistrict litigation (MDL) proceeding allege that they suffered either arterial cardiovascular injuries or injuries related to blood clots in the veins (venous thromboembolisms) as a result of taking prescription testosterone replacement therapy (TRT) drugs. Defendant AbbVie manufactures AndroGel, one of the TRT products at issue in this litigation.[1] In 2017, the parties selected for bellwether trials seven cases in which AbbVie is a defendant. The Court assumes familiarity with the proceedings in those cases. In 2018, the parties selected six additional bellwether cases in which AbbVie is a defendant for trial in the last quarter of 2018. Dominick Papandrea's case is in this group. Papandrea alleges that his use of AndroGel from September 2012 to November 2012 caused him to suffer a heart attack in November 2012. He has asserted claims against AbbVie for strict liability failure to warn; strict

[1] The AbbVie defendants include AbbVie Inc., AbbVie Products LLC, Abbott Laboratories, Inc., Abbott Products, Inc., Unimed Pharmaceuticals, Inc., Solvay Pharmaceuticals, SARL, Solvay Pharmaceuticals, Inc., and Solvay, S.A.

liability design defect; negligence; breach of implied warranty; breach of express warranty; fraud; and negligent misrepresentation. Papandrea's wife, plaintiff Joanne Papandrea, has also asserted a claim for loss of consortium.

AbbVie has moved to exclude the testimony of Dr. Hossein Ardehali regarding specific causation—that is, whether AndroGel was a substantial factor in causing Papandrea's heart attack. AbbVie has also moved for summary judgment on all of Papandrea's claims. For the following reasons, the Court denies AbbVie's motion to exclude Dr. Ardehali's specific causation testimony; grants AbbVie's motion for summary judgment on Papandrea's claims for negligence, breach of implied warranty, fraud, and negligent misrepresentation; and denies AbbVie's motion for summary judgment on all other claims.

Legal Standards

Federal Rule of Evidence 702 governs admissibility of expert testimony, and the district court acts as a gatekeeper in determining whether proposed expert testimony meets Rule 702's standards. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). The district court's gatekeeping role involves three steps: determining (1) whether the witness is qualified, (2) whether the expert's methodology is scientifically reliable, and (3) whether the testimony will assist the trier of fact to understand the evidence or determine a fact in issue. *See Myers v. Illinois Central R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010).

A party is entitled to summary judgment only if it shows that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). There is a genuine issue of material fact, and summary judgment is

precluded, "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In ruling on a motion for summary judgment, a court examines the record in the light most favorable to the non-moving party and draws all reasonable inferences in that party's favor. *Id.* at 255; *see also Parker v. Four Seasons Hotels, Ltd.*, 845 F.3d 807, 812 (7th Cir. 2017).

Discussion

The Court assumes familiarity with its prior orders but discusses them as necessary throughout this order. The Court also discusses facts necessary to resolve Papandrea's case and notes which facts are disputed.

A. Dr. Ardehali's specific causation opinion

The parties agree that New Jersey law governs Papandrea's claims. Under New Jersey law, Papandrea must prove that AndroGel was a substantial factor in causing his heart attack. *See* Defs.' Mot. for Summ. J. (Defs.' Mot.) at 1 (citing *James v. Bessemer Processing Co.*, 155 N.J. 279, 299 (1998)); Pl.'s Mem. in Opp. to Defs.' Mot. (Pl.'s Opp.) at 3. Papandrea relies on Dr. Ardehali's general and specific causation opinions to meet that burden.

AbbVie argues that the Court should exclude Dr. Ardehali's specific causation testimony. First, AbbVie contends that Dr. Ardehali does not reliably conduct a "differential etiology" because his decision to "rule in" AndroGel as a potential cause of Papandrea's heart attack was "not grounded in the existing science." Defs.' Mot. at 1. The Court has repeatedly held in this litigation that Dr. Ardehali's general causation opinion meets the *Daubert* standard and that he can rely on it to "rule in" AndroGel.

See, e.g., *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, MDL No. 2545, 2017 WL 1833173, at *13-*14, *17 (N.D. Ill. May 8, 2017) (*CMO 46*). The Court reaffirms its ruling and notes that in a separate order, it has rejected AbbVie's argument that new scientific evidence requires exclusion of all general causation opinions by plaintiffs' experts.

AbbVie also argues that Dr. Ardehali's specific causation opinion is unreliable because he admitted that Papandrea's risk factors were sufficient to cause his heart attack; Papandrea's treating doctors did not identify AndroGel as a cause of his heart attack; and Dr. Ardehali could not quantify AndroGel's risk in relation to other risk factors. The Court has previously ruled, and reaffirms now, that none of these issues is fatal to a specific causation opinion. *See, e.g.*, *CMO 46*, 2017 WL 1833173, at *17-*18; *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, MDL No. 2545, 2017 WL 6569632, at *9 (N.D. Ill. Dec.22, 2017). In conducting his differential etiology, Dr. Ardehali considered Papandrea's medical history and risk factors. Defs.' Mot., Ex. A (Ardehali Report) at 1-7. He was also aware that Papandrea filled his AndroGel prescription on September 24, 2012 and that Papandrea's heart attack resulted from "an acute thrombotic event at the site of ruptured plaque." *Id.* at 4, 10. Based on this information and his understanding of how testosterone affects biological mechanisms, Dr. Ardehali explained why Papandrea's use of AndroGel increased his risk of plaque rupture and of "increased thrombus size at the site of plaque rupture." *Id.* at 10-11. Dr. Ardehali also explained why Papandrea's "preexisting comorbid conditions" caused TRTs' "adverse effects" to be "more pronounced" and why his history of smoking was not a risk factor. *Id.*

This analysis is sufficient to satisfy *Daubert* and the specific causation requirements in Papandrea's case. *See, e.g.*, *CMO 46*, 2017 WL 1833173, at *20. AbbVie's citations to isolated portions of Dr. Ardehali's deposition transcript do not change this conclusion. Nor does AbbVie's argument that Dr. Ardehali improperly relied on the temporal proximity between Papandrea's AndroGel use and his heart attack, as it is clear that Dr. Ardehali's opinion is not "based solely on" that factor. *Id.* at *18. Dr. Ardehali's specific causation opinion is admissible, and AbbVie is not entitled to summary judgment on the ground that Papandrea lacks evidence sufficient to establish causation.

B. Scope of the New Jersey Product Liability Act (PLA)

AbbVie argues that the Court must dismiss Papandrea's claims for negligence, breach of implied warranty, fraud, and negligent misrepresentation because they are subsumed by the PLA. Papandrea concedes that the PLA subsumes his negligence and breach of implied warranty claims but argues that his fraud and negligent misrepresentation claims are beyond the PLA's reach.

The PLA defines a product liability action as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J. Stat. Ann. § 2A:58C-1(b)(3). The PLA defines the type of harm caused by a product to include, among other things, physical injury, pain and suffering, mental anguish, and loss of consortium. *See* N.J. Stat. Ann. § 2A:58C-1(b)(2). As for liability, the PLA provides:

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance

> standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

N.J. Stat. Ann. § 2A:58C-2.

The PLA's language "is both expansive and inclusive, encompassing virtually all possible causes of action [] relating to harms caused by consumer and other products." *Sinclair v. Merck & Co.*, 195 N.J. 51, 65, 948 A.2d 587, 595 (2008) (quoting *In re Lead Paint Litig.*, 191 N.J. 405, 436-37, 924 A.2d 484, 503 (2007)); *see also Sinclair*, 195 N.J. at 66, 948 A.2d at 596 (finding "clear legislative intent" that "the PLA is paramount when the underlying claim is one for harm caused by a product"). Thus in *Sinclair*, where "[t]he heart of plaintiffs' case [was] the potential for harm caused by Merck's drug," the court held that plaintiffs could not maintain a separate claim under the New Jersey Consumer Fraud Act. *Id.* And in *In re Lead Paint Litigation*, where defendants' alleged failure to warn of a product's dangers was the "central focus" of plaintiffs' claim for public nuisance, the court found that the PLA provided plaintiffs' exclusive remedy. 191 N.J. at 437, 924 A.2d at 503.

Drawing on these principles, "New Jersey state and federal courts have consistently dismissed product liability claims based on common law theories," including fraud and negligent misrepresentation, "when those theories allege harm caused by a product." *Bailey v. Wyeth, Inc.*, 424 N.J. Super. 278, 333, 37 A.3d 549, 583 (N.J. Super. Ct. Law Div. 2008), *aff'd sub nom*., *DeBoard v. Wyeth, Inc.*, 422 N.J. Super. 360, 28 A.3d 1245 (N.J. Super. Ct. App. Div. 2011); *see, e.g.*, *Bailey*, 424 N.J. at 334-35 & n.40, 37 A.3d at 583-84 & n.40 (PLA subsumed claims for fraudulent and negligent misrepresentation because, notwithstanding allegations that defendants misrepresented

or concealed information regarding drug's safety and efficacy, the claims at their core "involve[d] harm caused by" the drug); *McDarby v. Merck & Co.*, 401 N.J. Super 10, 96-97, 949 A.2d 223, 277 (N.J. Super. Ct. App. Div. 2008) (PLA subsumed consumer fraud claim for Merck's alleged "deception, fraud . . . misrepresentation, or . . . knowing concealment" of information regarding drug because at base, claim was for failure to warn; the failure to warn caused economic harm; and that "harm" "deriv[ed] from" physical and emotional injuries from use of drug); *see also Indian Brand Farms v. Novartis Crop Protection, Inc.*, 890 F. Supp. 2d 534, 547-48 (D.N.J. 2012) (*Novartis*).

Papandrea argues that the PLA does not govern his fraud and negligent misrepresentation claims because they "are based on AbbVie's conduct in promoting AndroGel off-label to treat age-related hypogonadism without disclosing" safety and efficacy information regarding such use. Pls.' Opp. at 3-4. Just as in *Bailey*, *McDarby*, and *Novartis*, however, "the heart of [Papandrea's] dissatisfaction" is his contention that AndroGel caused his injury. *Novartis*, 890 F. Supp. 2d at 547. Papandrea cites *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 602 (E.D. Pa. 2008), for the proposition that claims based on improperly marketing drugs—including through failure to disclose or concealing risks—"do not allege injury [caused] by [the drug] itself," but rather allege injury caused "by the allegedly faulty advertising campaign." *Id.* at 691. Although the court in *Knipe* indeed applied this logic in finding that the PLA did not subsume marketing-based claims, it did so based on *Wendling v. Pfizer*, No. A-1807-06T1, 2008 WL 833549 (N.J. Super. Ct. App. Div. Mar. 31, 2008). In *Wendling*, plaintiffs alleged that "the advertisement for defendant's veterinary product . . . was false and misleading because it stated that it would 'prevent and control parasites every day,' but it did not

prevent or control" the type of parasite that killed plaintiffs' horse. *Id.* at *1. Thus "it was not the product itself that caused the harm," but "its misleading promotion." *Id.* at *8; *see also Knipe*, 583 F. Supp. 2d at 618 (stating that in *Wendling*, "plaintiffs did not claim that the drug was not reasonably fit for its intended use because it failed to contain adequate warnings or instructions"); *Bailey*, 424 N.J. Super at 331 n.38, 37 A.3d at 581 n.38; *Novartis*, 890 F. Supp. 2d at 552. In *Knipe*, the court found that plaintiffs adequately alleged, in addition to their failure to warn claim, that defendants' advertising itself caused their injuries. *Knipe*, 583 F. Supp. 2d at 619. Here, by contrast, AbbVie's advertising cannot have caused Papandrea's injury unless AndroGel did. Unlike in *Wendling*, Papandrea alleges that AndroGel caused his injury and "was not reasonably fit for its intended use because of inadequate warnings." *Bailey*, 424 N.J. Super at 331 n.38, 37 A.3d at 581 n.38. The PLA thus subsumes Papandrea's claims for fraud and negligent misrepresentation. The Court therefore dismisses them, along with Papandrea's claims for negligence and breach of implied warranty. Papandrea's remaining claims are for failure to warn; design defect; breach of express warranty; and loss of consortium.[2]

C. Failure to warn

The PLA defines an adequate warning and establishes "a rebuttable presumption" of adequacy for a drug warning label that the FDA has approved. N.J.

[2] Although Papandrea states that the PLA "subsume[s]" his strict liability claims, Pls.' Opp. at 3, the Court does not read this as a concession that his failure to warn and design defect claims should be dismissed. AbbVie does not argue these claims should be dismissed as subsumed, and as the New Jersey Supreme Court has stated, the PLA's theory of recovery "is, for the most part, identical to strict liability." *In re Lead Paint Litig.*, 191 N.J. at 436, 924 A.2d at 503 (citation omitted).

Stat. Ann. § 2A:58C-4. The "presumption is not absolute." *Perez v. Wyeth Labs., Inc.*, 161 N.J. 1, 24, 734 A.2d 1245, 1259 (1999). To overcome the presumption, a plaintiff must show specific proof of "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects." *Perez*, 161 N.J. at 25, 734 A.2d at 1259; *see also Kendall v. Hoffman-La Roche, Inc.*, 209 N.J. 173, 195, 36 A.3d 541, 554-55 (2012). Alternatively, a plaintiff must show proof of "manipulation of the post-market regulatory process." *Cornett v. Johnson & Johnson*, 211 N.J. 362, 388, 48 A.3d 1041, 1056 (2012), abrogated on other grounds by *McCarrell v. Hoffman-La Roche, Inc.*, 227 N.J. 569, 153 A.3d 207 (2017); *see also McDarby*, 401 N.J. Super. at 63-64, 71, 949 A.2d at 256-57, 261 (recognizing "flaws in [FDA's] post-marketing oversight process" that were not before the court in *Perez*, and finding that presumption can be overcome with "substantial evidence" of "economically-driven manipulation of the post-market regulatory process").

AbbVie argues that it is entitled to the rebuttable presumption of adequacy because the FDA approved AndroGel's label. Papandrea contends that the presumption is inapplicable because there is evidence that (1) AbbVie marketed AndroGel for treatment of age-related hypogonadism, an off-label use, and (2) the FDA did not approve AndroGel's label for that use. Papandrea cites, among other things, deposition testimony from his regulatory expert, Dr. David Kessler, that when AbbVie sought FDA approval for AndroGel, it "plan[ned] to market for andropause" but "submit[ted] an application" in which andropause was "not part of [the] labeling." Pl.'s Opp., Ex. 1 at 139:8-19. Papandrea also points to the opinions of another regulatory expert, Dr. Peggy Pence, that the FDA did not approve AndroGel for age-related

hypogonadism and that AbbVie nonetheless marketed AndroGel for that use. Pl.'s Opp., Ex. 3 at 30, 58. Additionally, AbbVie records show that its sales representatives discussed AndroGel marketing materials with Papandrea's prescribing physician, Dr. Michael Cascarina. Pl.'s Opp., Ex. 13. Papandrea contends that these materials encouraged physicians to prescribe AndroGel for age-related hypogonadism. Pl.'s L.R. 56.1 Stat. ¶ 14. AbbVie concedes that "age-related hypogonadism" has never appeared in the indications section of AndroGel's label but disputes the scope of the approved indication and denies that it marketed AndroGel for off-label purposes. *See, e.g.*, Defs.' Resp. to Pl.'s L.R. 56.1 Stat. ¶¶ 3, 10.

Viewed in the light most favorable to Papandrea, this evidence demonstrates that whether AbbVie promoted AndroGel for an off-label use, and whether the FDA approved the warning label for that use, are disputed factual issues. Neither party has identified clear guidance from the New Jersey Supreme Court regarding whether AbbVie is entitled to the presumption under these circumstances, and this Court has found none.[3] As the court in *Knipe* stated, however, "[o]ff-label uses of approved medications have not been subjected to the baseline FDA scrutiny." 583 F. Supp. 2d at 631 (internal quotation marks and citation omitted). It would be illogical, the court continued, to apply the presumption in a manner that allows a drug manufacturer to "hide behind an FDA-approved warning" for an approved use "when the FDA never had the opportunity, during the pertinent period, to review the propriety of a proposed

[3] In *Cornett*, the court suggested that in this situation, the presumption might apply but could be overcome. 211 N.J. at 390, 48 A.3d at 1057. The case was decided at the motion to dismiss stage, however, and there is no indication that the parties disputed whether the presumption applied in the first place.

warning with respect to" the off-label use. *Id.* The Court agrees with this reasoning and "declines to find the presumption of adequacy conclusively applicable." *Id.*

AbbVie argues that *Seavey v. Globus Medical, Inc.*, Civil No. 11-2240 (RBK/JS), 2014 WL 1876957 (D.N.J. Mar. 11, 2014), compels the opposite conclusion. There, the court stated that even if plaintiff had provided evidence that defendant had marketed its device for off-label use, the evidence "would not support a product defect case for inadequate warning." *Id.* at *9; *see also id.* (stating that because the FDA "does not regulate" physicians' use of medical devices, "a manufacturer has no affirmative duty to intervene in order to prevent off-label use of its product"). The Court finds *Seavey* both distinguishable and, respectfully, unpersuasive. First, unlike in this case, the plaintiff did not offer evidence of off-label promotion. *See id.* at *9. Second, the court analyzed the statutory presumption through the lens of the FDA's relationship with physicians, but the purpose of the presumption is to protect consumers by encouraging manufacturers' cooperation with the FDA on drug labeling. *See, e.g.*, *Perez*, 161 N.J. at 25, 734 A.2d at 1259 (the presumption is that the manufacturer's "duty to consumers is met by compliance with FDA regulations").

Even if AbbVie is entitled to the presumption, Papandrea has shown that whether he can overcome it under the *McDarby* exception is a disputed factual issue.[4] As AbbVie notes, the court in *Bailey* stated that plaintiffs could not "use the fact that [a drug] was prescribed off-label to rebut the statutory presumption of adequacy." 424 N.J. Super. at 322-23, 37 A.3d at 576. But the plaintiffs in *Bailey* did not provide evidence

[4] Papandrea does not argue that he can overcome the presumption under the *Perez* exception, *see* Pl.'s Opp. at 6-7, so the Court does not address whether he can.

that the manufacturer *promoted* its drug for off-label use. Papandrea argues that AbbVie has engaged in off-label promotion. Additionally, he has offered expert testimony that by 2007, AbbVie was on notice of a potential association between AndroGel use and heart attacks. *See, e.g.*, Pl.'s Opp., Ex. 3 at 79-85. And he has offered documentary evidence that AbbVie did not update the label (or seek a modification) to reflect that risk until the FDA required the change in 2015. Pl.'s Opp., Ex. 11 (AndroGel label revised April 2011); *id.*, Ex. 9 (March 2015 FDA drug safety communication); *id.*, Ex. 12 (AndroGel label revised May 2015). Although AbbVie disputes that AndroGel is causally associated with heart attacks and that it promoted the product for an off-label use, a reasonable jury could disagree. Weighing the evidence, a jury could find that AbbVie "actively, and to an extent successfully, sought to dilute the labeling" required in light of safety information it knew, and thus engaged in "manipulation of the post-market regulatory process." *McDarby*, 401 N.J. Super. at 63, 68, 949 A.2d at 256, 259; *see also Knipe*, 583 F. Supp. 2d at 632-33. A reasonable jury could also find that the label in effect at the time Papandrea took AndroGel did not "communicate[] adequate information on the dangers and safe use of the product." N.J. Stat. Ann. § 2A:58C-4. Because factual disputes remain on these issues, the Court denies AbbVie's motion for summary judgment on Papandrea's failure to warn claim. *See Anderson*, 477 U.S. at 248.

D. Design defect

AbbVie argues that under New Jersey law, a plaintiff cannot prevail on a design defect claim without offering evidence of a feasible alternative design. Defs.' Mot. at 8 (citing *Lewis v. Am. Cyanamid Co.*, 155 N.J. 544, 715 A.2d 967 (1998)). According to

AbbVie, summary judgment in its favor is appropriate on this claim because Papandrea has offered no such evidence.[5] In *Lewis*, however, the court stated that a plaintiff asserting a design defect claim must provide evidence from which a reasonable jury could find "*either* that the product's risks outweighed its utility *or* that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm." *Lewis*, 155 N.J. at 570, 715 A.2d at 980 (emphasis added). New Jersey courts have adopted a seven-factor risk-utility test "as a means of determining whether a product is defectively designed." *Johansen v. Makita U.S.A., Inc.*, 128 N.J. 86, 95, 607 A.2d 637, 642 (1992). A jury must "impose liability on the manufacturer if the danger posed by the product outweighs the benefits of the way the product was designed and marketed." *Id.* "[T]he prevalent view is that, unless one or more of the other factors might be relevant in a particular case, the issue upon which most claims will turn is the proof by plaintiff of a 'reasonable alternative design[.]'" *Cavanaugh v. Skil Corp.*, 164 N.J. 1, 9, 751 A.2d 518 (2000) (quoting *Green v. Gen. Motors Corp.*, 310 N.J. Super. 507, 517-18, 709 A.2d 205, 210 (N.J. Super. Ct. App. Div. 1998)). Some courts, however, have recognized that a plaintiff may prevail on a design defect claim by proving that the product is "'so dangerous and of such little use that under the risk-utility analysis [the] manufacturer [should] bear the cost of liability to others,'" notwithstanding the absence of an alternative design that "would have made a product safer." *Truchan*

[5] The Court disagrees with AbbVie's suggestion that, in light of the order on the Besins defendants' motion for summary judgment, Papandrea is precluded from arguing that a design defect claim can survive without evidence of a feasible alternative design. *See* Defs.' Mot. at 8-9. The Court understood plaintiffs' concession as limited to the claims against Besins. *See In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, MDL No. 2545, 2018 WL 2416239, at *3 (N.D. Ill. May 29, 2018).

v. Nissan Motor Corp. in U.S.A., 316 N.J. Super. 554, 563-64, 720 A.2d 981, 985-86 (N.J. Super. Ct. App. Div. 1998) (quoting *Smith v. Keller Ladder Co.*, 275 N.J. Super. 280, 286, 645 A.2d 1269, 1272 (N.J. Super. Ct. App. Div. 1994)); *Appleby v. Glaxo Wellcome, Inc.*, No. Civ. 04-0062 RBK, 2005 WL 3440440, at *6 (D.N.J. Dec. 13, 2005).

Papandrea argues that AndroGel use is associated with the risk of heart attacks; AndroGel's safety and efficacy for treatment of age-related hypogonadism have not been established; Papandrea is no longer the kind of patient for whom Dr. Cascarina prescribes AndroGel; and if AndroGel's label had warned of a specific risk of heart attack in 2012, it is possible that Dr. Cascarina would not have prescribed him the drug. *See* Pl.'s Opp., Ex. 2 (Ardehali General Report) at 6-10; Pl.'s Opp., Ex. 4 (Cascarina Dep.) at 154:14-157:15, 206:9-207:20. This evidence is relevant to several risk-utility factors, including AndroGel's usefulness, its likelihood of causing injury, and Papandrea's awareness of its inherent dangers "because of . . . the existence of suitable warnings or instructions." *Johansen*, 128 N.J. at 96, 607 A.2d at 643. AbbVie disputes this evidence, but reasonable minds could differ. Whether AndroGel's dangers outweigh its benefits is a disputed issue, and the Court therefore denies AbbVie's motion for summary judgment on Papandrea's design defect claim. *Anderson*, 477 U.S. at 248.

E. Breach of express warranty

In order to prevail on a claim for breach of express warranty, Papandrea must establish that (1) AbbVie "made an affirmation of fact, promise, or description about the product; (2) this affirmation of fact, promise, or description became part of the basis of

the bargain for the product; and (3) the product ultimately did not conform to the affirmation of fact, promise, or description." *In re Avandia Marketing Sales Practices & Prods. Liab. Litig.*, 588 F. App'x 171, 175 (3d Cir. 2014) (citing N.J. Stat. Ann. § 12A:2-313). Papandrea must show "[p]roof of causation," but "'mere failure of promised performance is enough without proof of any defect.'" *Ford Motor Credit Co., LLC v. Mendola*, 427 N.J. Super. 226, 242, 48 A.3d 366, 375 (quoting *Realmuto v. Straub Motors, Inc.*, 65 N.J. 336, 343, 322 A.2d 440 (1974)).

AbbVie argues that Papandrea must, but cannot, prove that he "read, saw, or heard the representations at issue." Defs.' Mot. at 10. Although Papandrea testified that he did not research AndroGel or see advertisements before taking the drug, he also testified that he understood the instructions that came with his prescription and that he "was aware . . . about the consequences, the results, you know, the bad stuff about it . . . . all the side effects that it could cause." Pl.'s Opp., Ex. 5 at 122:17-123:21, 130:2-15. Even assuming Papandrea must prove that he directly relied on AbbVie's representations, a reasonable jury could determine based on this testimony that he did.

AbbVie next argues that Papandrea cannot support his claim with representations allegedly made to Dr. Cascarina. But in this MDL, the Court has denied AbbVie's motions for summary judgment on several plaintiffs' express warranty claims, including because plaintiffs had "provided evidence of specific affirmations that AbbVie representatives made to [their] prescribing physicians." *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, 2017 WL 1836443, at *9 (N.D. Ill. May 8, 2017). AbbVie has cited no authority, and the Court is aware of none, to the effect that such evidence cannot support Papandrea's breach of

express warranty claim under New Jersey law. AbbVie points the court to *Mendez v. Shah*, 94 F. Supp. 3d 633 (D.N.J. 2015), where, in dismissing plaintiff's express warranty claim, the court appears to have discounted plaintiff's allegation that "her doctor relied upon the [drug manufacturer's] warranties." *Id.* at 640. But the court ultimately dismissed the claim because plaintiff "had not identified *any* examples of a false affirmation or promise" made to her or to anyone else. *Id.* (emphasis added).

In this case, by contrast, there is undisputed evidence that AbbVie sales representatives visited Dr. Cascarina 142 times before he prescribed AndroGel to Papandrea. Although AbbVie disputes that the representatives discussed AndroGel on every occasion, Dr. Cascarina testified that he recalled a sales representative talking to him about AndroGel "probably . . . every two weeks." Cascarina Dep. at 126:14-21. He also testified that he reviewed materials the sales representatives left for him. *Id.* at 126:22-127:10. AbbVie's records show that those materials included the HIM study and the ADAM questionnaire which, according to Papandrea, encouraged prescribing AndroGel for age-related hypogonadism. *See* Pl.'s Opp., Ex. 13; Pl.'s L.R. 56.1 Stat. ¶ 14. And although Dr. Cascarina testified that he had no memory of the HIM study or of specific conversations about the ADAM questionnaire, he also testified that some of the ADAM questions sounded familiar and that he "remember[ed] a lot of talk . . . about fatigue and low sex drive concerning . . . low testosterone and its replacement." Defs.' Reply, Ex. E at 235:9-238:23. Finally, Papandrea testified that he relied on Dr. Cascarina's judgment when he decided to take AndroGel. Papandrea Dep. at 130:1-131:6. Based on this evidence, a reasonable jury could find that AbbVie made affirmations to Dr. Cascarina about AndroGel's safety and efficacy for treating age-

related hypogonadism and that the affirmations "became part of the basis of the bargain" for Papandrea's AndroGel use. *In re Avandia*, 588 F. App'x at 175. Based on Dr. Ardehali's testimony that AndroGel was a substantial factor in causing Papandrea's heart attack, a reasonable jury could also find that AndroGel "ultimately did not conform to" AbbVie's affirmations. *Id.* The Court therefore denies AbbVie's motion for summary judgment on Papandrea's express warranty claim.

F. Loss of consortium

The Court denies AbbVie's motion for summary judgment on Papandrea's loss of consortium claim because it is derivative of surviving claims.

Conclusion

For the foregoing reasons, the Court denies AbbVie's motion to exclude Dr. Ardehali's specific causation testimony, grants AbbVie's motion for summary judgment on Papandrea's claims for negligence, breach of implied warranty, fraud, and negligent misrepresentation, and denies AbbVie's motion for summary judgment on Papandrea's claims for strict liability failure to warn, strict liability design defect, breach of express warranty, and loss of consortium [dkt. no. 20].

MATTHEW F. KENNELLY
United States District Judge

Date: August 23, 2018